

Remarks

This case, after having been fully and fairly prosecuted to a focused Appeal, has been remanded to the Examiner for yet another attempted rejection. The rejection of this method claim bears no better than the previous one.

This application is a Divisional of U. S. Application Serial No. 10/272,382 having been restricted out by a restriction from the parent case. Claim 1 has been limited to 1:1 neutral complexes, that is, a complex containing one ion of the trace element for each molecule of the dicarboxylic alpha amino acid, with the molecule of the complex carrying a net zero charge. Bases for this limitation is provided in the specification pointing out that 1:2 complexes are less effective pronutrients, having a lower metal content, and more costly than 1:1 complexes formed in the present invention. The amino acid ligand serves a dual role as a bidentate ligand that forms a 1:1 complex with metal ion, and acts as the counter ion to balance the charge on the cationic complex of the metal and amino acid carboxyl moiety.

Claim Rejection - 35 U.S.C. § 112

In claim 1, the Examiner objects on the basis that the phrase "an essential trace element . . . to an animal" is vague. Applicants respectfully traverse this rejection.

The term "an essential trace element" has a specific meaning that is generally accepted and known and understood by individuals engaged in the field of nutrition at a date much earlier than the filing date of the present invention. The term refers to those elements that are present in animal, as well as human, tissues and diets in amounts smaller than that of other macronutrient elements, such as sodium, potassium, calcium, magnesium, and phosphorous. The essentiality of a trace element is established by regulatory agencies and scientific communities. In the United States, the National Research Council (NRC) issues its findings and recommendations after

reviewing available studies that demonstrate the essentiality of a specific element in a number of species. The studies upon which the NRC bases its recommendations are rigorous, and well designed and executed.

There are many references to "trace element" which support that the term is far from ambiguous and is widely used and relied upon in the field of nutrition. Examples include: 1) an international symposium that is held every two to three years entitled "Trace Element Metabolism in Man and Animal, TEMA;"¹ 2) a scientific journal entitled "Biological Trace Element Research" which is published semi-monthly by Human Press, Inc., Totowa, New Jersey; 3) a scientific journal entitled "Journal of Trace Elements in Experimental Medicine" which is published quarterly by Wiley-Ross, Hoboken, New Jersey; 4) a scientific journal entitled "Journal of Trace Elements in Medicine and Biology" which is published quarterly by Urban & Fisher Verlag, Jena, Germany; and 5) a scientific journal entitled "Trace Elements and Electrolytes" which is published quarterly by Dustri-Verlag, Dr. Karl Feistel, Muenchen, Germany. The list goes on, but the point is made that the term is one commonly known and recognized in the field of the invention and is far from ambiguous. See *Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996) (citations omitted) ("[a] technical term used in a patent documents is interpreted as having the meaning that it would be given by persons experienced in the field of the invention . . . "); see also *National Tractor Pullers Ass'n, Inc. v. Watkins*, 205 U.S.P.Q. 892, 913 (N.D. Ill. 1980) (citation omitted) (reasoning that where there is language as precise as the subject matter permits and those skilled in the field can reasonably appraise the meaning, an area of uncertainty is not sufficient justification to deny the

¹ TEAM 1, the first symposium, was held June 1969 in Aberdeen, U.K.; the latest symposium, TEMA 12, was held June 2005 in Colraine, Northern Ireland.

patentee). Thus, the Examiner's objection should be withdrawn as the term "essential trace element" is known and used in the field of the invention, and supports the scope of the claim as definite.

With respect to Examiner's comment regarding vagueness of the phrase "an essential trace element ... to an animal," the Examiner's interpretation of the information in the referenced text and table is incorrect. The Examiner uses as a reference for the objection a table in a textbook which is a secondary source. This table summarizes the nutrient requirements for maintenance, and lists the NRC Nutrient Requirements of Domestic Animals as the source of the information. Secondary sources are often incomplete and may be inaccurate. For example, the table the Examiner cites does not provide the requirements for sodium, potassium, magnesium, sulfur, iron, zinc, manganese, copper, iodine, cobalt and selenium for beef cattle, but does give the information for dairy cattle. Does this mean that these nutrients are not essential for beef cattle, but are essential for dairy cattle? Not necessarily. Information could be missing for one of many reasons. It is possible that the exact requirements for "maintenance" have not been established by the NRC due to lack of sufficient information, or the requirements have been established and are listed in the primary source, "Nutrient Requirements for Domestic Animals," but the author of the text could not find the information or chose not to include it in the article.

The Examiner's objections as to the requirements of essential trace elements ignore the well established knowledge at least by the time of the effective filing date of this case regarding nutrient requirement of animals. The essentiality of an element is often determined based on studies that demonstrate the development of deficiency symptoms consistent with the known biological role of the trace element if the animal is fed diets that are void of the trace element. Often, it is stated in the scientific literature that a trace element is found to be essential in a given

list of species. This does not mean that the trace element is essential only in the species on the list and is not essential in the species not included on the list. It only means that these are the only species for which sufficient information is available to demonstrate essentiality. Other species have not been studied at all or sufficient information is currently not available. Once it is demonstrated that an element is essential in humans and animals, studies are undertaken to determine exact requirements.

The exact requirements of a trace element depend on the species, the time in the life cycle of the animal, the nature and amount of other nutrients in the diet, and the desired outcome of the feeding program. The Committee on Animal Nutrition of the National Research Council publishes a series of volumes entitled "Nutrient Requirements of Domestic Animals." Each volume addresses a specific domestic animal group. For example, one volume provides information on "Nutrient Requirements of Swine;" another "Nutrient Requirements of Dairy Cows." These volumes are comprehensive and demonstrate that it is impossible to accurately present the requirements of all essential trace elements in the context of a claim in a patent application. Rather, the term is understood as used by one of skill in the art. Thus, the Examiner's objections should be withdrawn as the term "essential trace element . . . to an animal" provides sufficient information to describe the requirements of essential trace elements with respect to various animals without listing the species.

Applicants respectfully request that the rejection to claim 1 under 35 U.S.C. § 112 be withdrawn.

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Conclusion

For all of the above stated reasons, it is believed this application is in *prima facie* condition for allowability. Allowance is respectfully requested.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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